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SOP 426
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ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

S.C. BISTRI-VET SRL
LIBERTATII STR. 13
420155 BISTRITA (JUD. BISTRITA-NASAUD)
ROMANIA

Hoogstraten, 09.10.2018

ORIGINAL

Material

C614100-001079-01 AMOXY-KEL 15% 100 ML

Pharmaceutical Form:

Sterile suspension

Batch 4002249 / Manufacturing Date 08.2018 Expiry date 08.2021

Inspection lot 40000036794 from 08.2018

CERTIFICATION STATEMENT: I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.

Formula: Amoxycillin trihydrate eq.150 mg amoxycillin base excipients q.s.ad 1 ml

Aspect: white to pale yellow suspension

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (100 ml)	%	99,76	98,00	102,00
Resuspendability	ROT	18		20
Relative density		0,983	0,950	1,000
Viscosity	mPa.s	61	20	200
Needling time	s	12		30
Id: Amoxicillin trihydrate		Complies		
Id: Butylhydroxytoluene		Complies		
Assay: Amoxicillin	%	98,59	95,00	105,00
Assay: Butylhydroxytoluene	%	99,83	90,00	110,00
Sterility		Complies		

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Dig. Sign.: Van Buggenhout Kris
04.09.2018 16:29:31

Qualified Person

Conclusion:
Quality test complied